Docket No.: 0020-5305PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Tomohiko KUBO et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: October 1, 2004

Art Unit: N/A

For: LIQUID DRUG CONTAINER

Examiner: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The PTO is requested to use the amended sheets/claims attached hereto (which correspond to Article 19 amendments or to claims attached to the International Preliminary Examination Report (Article 34)) during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: October 1, 2004

Respectfully submitted,

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AMENDMENT

(Amendment under Article 11 of the Law)

To: Commissioner of the Patent Office

1. Identification of the International Application PCT/JP03/04318

2. Applicant

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4. Item to be Amended: DESCRIPTION and CLAIMS

5. Subject matter of Amendment As per the attached sheets

(1) Replace " Examined Japanese utility model publication No. S63" on page 3, lines 17-18 of description with "Published Japanese utility model application No. S63"

(2) Replace "senshou (interference)" on page 22, line 3 of description with "kanshou (interference)"

(3) Claims 1-4 and 7-10 have been amended as mentioned below and renumbered as claims 1-4 and 8-10. New claim 1 is the one prepared by combination of original claims 1, 2, 4 and parts of claims 3 and 8. Claim 2 has been rewritten on the basis of descriptions on page 20, lines 6-26 and drawings (especially, Fig. 2, Fig. 6 and Fig. 10). Claim 7 has been rewritten on the basis of descriptions on page 9 line 25 to page 10, line 4 and page 24, lines 1-18. Claim 8 has been rewritten on the basis of description on page 24, lines 1-18. Claim 9 is the one prepared by partial amendment of original claim 8. Claim 10 has been rewritten on the basis of description on page 20, lines 6 to page 21, line 1.

It is hereby stated that claims 1-4 and 7-10 have been amended within the materials written in description, claims or drawings at the time of filing of International application.

6. List of Attached Documents

1. Substitute sheets of Description, page 3 and 22
2. Substitute sheets of claims, pages 34 - 38

liquid drugs applied to eye tissues or organs sensitive to stimulus.

In recent years, reports have been made on so-called chemical hypersensitivity, i.e., symptom of serious allergy to chemical compounds such as preservative. For that reason, some chemicals and cosmetics containing no preservative have been developed and put to practical use. However, if the chemicals or cosmetics do not contain any preservative, it is impossible to ensure aseptic conditions after unsealing. This necessitates packaging of a dosage of such a chemical solution or a liquid cosmetic in a single disposable container, entailing an increase in production costs and space-consuming. Thus, the chemicals and cosmetics do not contain any preservative fail in popularization.

On the other hand, it has been proposed to make the container with a plastic deformable body (Published Japanese utility model application No. S63-184037, Japanese translation of PCT international application No. 2001-521865) to prevent invasion of floating bacteria or microorganism, which results from inflow of the atmosphere which occurs at the time of restoring of the pressure-deformed container to its original state by the pressure release after discharge of the liquid drug.

However, even if the container is of plastic

positioning rib for the hydrophobic filter 4.

In the present embodiment, the hydrophilic filter 3 and hydrophobic filter 4 do not cause interference with each other since they are separately arranged on the top and bottom sides of the filter-mounting member 8. Further, it is possible to use large sized filters 3 and 4 unless the diameter of each filter 3, 4 exceeds the diameter of filter-mounting member 8.

In this way the diameter of hydrophilic filter 3 which directly have an influence on easiness of discharge easiness of liquid drug was enlarged to the inner diameter of skirt portion 82 of filter-mounting member 8. Thus, the present embodiment make it possible to realize considerably good discharge characteristics of the liquid drug even if the hole of the hydrophilic filter 3 is reduced in diameter.

As the filters 3 and 4, there have been used such filters each having a bore size of 0.45 μm or below, preferably, 0.22 μm or below to prevent contamination source bacteria from invading the interior of the container. The trapping mechanism of the filter is classified broadly into two categories, i.e., a "depth type" that traps bacteria within the filter, and a "screen type" that traps bacteria on surfaces of the filter. Any type of the filter can be used for the present invention.

CLAIMS

1(Amended). A liquid drug container comprising a container body having a mouth and being deformable under the pressure, a cap-shaped nozzle member liquid-tightly mounted on the mouth of the container body, and a nozzle cap mounted on the nozzle member, wherein said nozzle member comprising a top wall covering the mouth of said container body, a skirt portion extending from a peripheral portion of the top wall toward a proximal end of the nozzle member, and a nozzle extending from a central portion of said top wall toward a distal end of the nozzle member, and wherein said nozzle member has a nozzle hole that passes through the top wall and discharges a liquid drug contained in said container body, and an air hole passing through the top wall at a position separate from said nozzle hole and communicating an interior of said container body to the outside thereof, wherein said nozzle member may be provided with a disk-shaped filter-mounting member in said skirt portion, wherein the top wall of said nozzle member or said disk-shaped filter-mounting member being provided with sets of grooves respectively communicated with said nozzle hole and said air hole, wherein said top wall or filter mounting member is provided with a hydrophilic filter and a hydrophobic filter by welding so that said hydrophilic

filter covers said nozzle hole and said set of grooves communicated with said nozzle hole, while the hydrophobic filter covers said air hole and the set of said grooves communicated with said air hole.

2(Amended). The liquid drug container according to claim 1, wherein each set of grooves include radial grooves communicated with the nozzle-communicating hole and annular grooves communicated with the radial grooves.

3(Amended). The liquid drug container according to claim 1, wherein said hydrophilic filter and a hydrophobic filter are in the form of a flat membrane.

4(Amended). The liquid drug container according to claim 1, wherein said nozzle member is provided on the inner side of said top wall with a set of grooves communicated with said nozzle hole and a set of grooves communicated with said air hole, and wherein a hydrophilic filter and a hydrophobic filter respectively covering each set of grooves are welded to the inner side of said top wall.

5. The liquid drug container according to claim 1, wherein said hydrophilic filter and hydrophobic filter have a bore size of 0.45 μm or below.

6. The liquid drug container according to claim 5, wherein said hydrophilic filter and hydrophobic filter have a bore size of 0.22 μm or below.

7(Amended). The liquid drug container according to claim

1, wherein said hydrophilic filter is arranged on one side of said top wall or filter mounting member, while the hydrophobic filter is arranged on the opposite side of said top wall or filter mounting member.

8(Amended). The liquid drug container according to claim 7, wherein said nozzle member is provided on one side of its top wall with a set of grooves communicated with said nozzle hole, and on the opposite side with a set of grooves communicated with said air hole.

9(Amended). The liquid drug container according to claim 7, wherein said nozzle member is provided with a disc-shaped filter-mounting member that is arranged in the skirt portion and in close contact with an inner side of its top wall, wherein said disk-shaped filter-mounting member is provided with a nozzle-communicating hole and an air-communicating hole each being communicated with said nozzle hole or air hole, and wherein said filter-mounting member is provided on its one side with a set of grooves communicated with said nozzle hole through said nozzle-communicating hole, and on the opposite side with a set of grooves communicated with said air hole through said air-communicating hole, and wherein said filters are respectively welded to the disc-shaped wall.

10(Amended). The liquid drug container according to claim 9, wherein each set of grooves include radial grooves

communicated with the nozzle-communicating hole and annular grooves communicated with the radial grooves.

11. The liquid drug container according to claim 1, wherein the nozzle member is provided with a flow control member that controls air flowing into the container body from the outside through the air-communicating hole.

12. The liquid drug container according to claim 11, wherein said nozzle member comprises a top wall covering the mouth of said container body, and a skirt portion extending from a peripheral portion of said top wall, and wherein said nozzle member is provided with a flow control member that controls air flowing into the container body from the exterior of the container body, said flow control member being arranged in the air hole provided in said top wall of the said nozzle member.

13. The liquid drug container according to claim 11, wherein said nozzle member is provided with a filter-mounting member having a nozzle-communicating hole communicated with the nozzle hole and an air-communicating hole communicated with the air hole, and wherein said filter-mounting member is provided with the hydrophilic filter covering said nozzle-communicating hole, and the hydrophobic filter covering said air-communicating hole, said air-communicating hole being provided with a flow control member that controls the air flowing into the

container body from the exterior of the container body.

14. The liquid drug container according to claim 11, wherein said flow control member is a check valve.

15. The liquid drug container according to claim 11, wherein said flow control member is a diaphragm.